New Mandibular Advancement Device (BestMAD) in the Treatment of Obstructive Sleep Apnea: A Preliminary Study

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Abstract

Background: Oral appliances have emerged as an important alternative in treating patients with mild-moderate obstructive sleep apnea (OSA). They are effective, simple to use and well tolerated by the patient compared to other therapeutic solutions, such as continuous positive airway pressure (CPAP) or surgery of the upper airways. Aim: The aim of this preliminary study was to assess the effectiveness of a new mandibular advancement device, the BestMAD, in the treatment of OSA patients.

Materials and methods: We selected 10 patients, 9 males and 1 female, with an average age of 51.5 years, affected by OSA, with a BMI (Body Mass Index) value ≤25 kg/m2. All patients used the BestMAD for at least 6 months. A control polysomnography was repeated after 6 months and a questionnaire was administered to assess the side effects eventually felt by the patient.

Results: After treatment with BestMAD, a statistically significant improvement was found in AHI (p=0.0051), RDI (p=0.0051) and ESS (p=0.0049). With regard to adherence to the treatment, 8 patients claimed to have used the BestMAD for the entire duration of nocturnal rest, while the remaining 2 only for a few hours at night.

Conclusions: BestMAD is a comfortable device which has proved effective in improving the polysomnographic parameters.

Keywords: Obstructive sleep apnea; Oral appliance; Mandibular advancement device

Introduction

Obstructive sleep apnea (OSA) is a common clinical condition affecting 2-26% of the general population [1,2]. It is characterized by partial or complete obstruction of the upper airways during sleep, resulting in repetitive events of apnea and hypopnea with a consequent negative impact on the health and the behavior of patients [3,4]. Furthermore, OSAS is considered today a cardio-metabolic disease with a great impact on public health, related to increased risk of hypertension, cardiovascular disease and mortality, metabolic imbalance and cerebrovascular accidents [5-7]. The treatment with continuous positive airway pressure (CPAP) is considered the gold standard, but some patients find it intolerable [8]. A study assessing compliance with CPAP, found that only 46% of patients used the device for more than 4 hours per night for more than 70% of the nights [9]. For patients with mild or moderate OSA, oral appliances may be appropriate therapy as suggested by the Standards of Practice Committee of the American Academy of Sleep Medicine and the Deutsche Gesellschaft für Zahnarztliche Schlafmedizin [10,11]. In recent years, several clinical randomized trials compared the effectiveness of treatment with CPAP and oral devices [12,13]. Although CPAP demonstrated superior efficacy in terms of apnea-hypopnea index (AHI) reduction, self-reported compliance with oral appliance was higher. The resulting effects on clinical outcomes in patients with mild, moderate or severe OSA were equivalent or better in the oral appliance. These devices are designed to increase the pharyngeal airway space (PAS) by three fundamental mechanisms: 1) the protrusion of the jaw and the tongue away from the back wall of the pharynx; 2) the stabilization of the jaw and the inhibition of the opening of the mouth, allowing the anterior positioning of the hyoid bone and the tongue; 3) the implementing of the vertical dimension to induce a reflex at the level of the TMJ, which activates the genioglossus muscle and tends to extend the tongue [13-16]. On the basis of scientific assessments and international guidelines, the use of the protrusion guides is recommended for the treatment of sleep-related breathing disorders as an alternative choice after a previous attempt treatment with CPAP, or as initial therapy in the presence of primary snoring, upper airway resistance syndrome (UARS), mild-moderate OSA with little symptoms in conditions of sufficient intraoral anchorage [17]. More than 60 different oral appliances are in use, with considerable variations in design [18-21]. Mandibular advancement devices (MAD) have been the most intensely researched, and their effectiveness documented by the Cochrane Collaboration as the
highest level of scientific evidence [22,23]. In 2007, Dr. Enzo Iacomino, Dr. Vittorio Bisogni and the expert in orthodontic technique Mr. Franco Pestilli developed the BestMAD, a device for mandibular and tongue base advancement for the treatment of OSA in patients intolerant to CPAP, alone or in combination with other therapeutic options. The device was clinically applicable since 2008. The purpose of this study was to evaluate the effectiveness of BestMAD in the treatment of patients with OSA.

Materials and Methods

BestMAD

The BestMAD is a tailor-made patient device, structured in two arches that run on each other (Figure 1).

Figure 1: BestMAD determines a mandibular and tongue base advancement associated with the activation of the genioglossus muscle. It reduces the resistance of the upper airways, expanding the size of the oropharyngeal lumen and is therefore indicated for the symptomatic treatment of sleep apnea and snoring.

The part in contact with the teeth and the gingival mucosa (1 mm) is soft and made of vacuum-polyurethane, while the outside part is rigid and made of copolyester completed with acrylate (1 mm). An adjustable screw (MDSA® Pty Ltd, Australia) joins the two arches, and the protrusion is adjustable from a minimum of 4 mm to a maximum of 10 mm (2 mm in crackdown) (Figure 2).

The screw provides lateral movements (compatible with any physiological movements during the REM stage of sleep) (Figure 3) the initial adjustment of the protrusion is established on clinical and radiological data and is generally of 6 mm.

It is not advisable to exceed 10-12 mm in protrusion. A proprioceptive indicator or oral tongue stimulator (Figure 4) was included in the device as reference point for the anterior positioning of the tongue.

Figure 2: The screw connecting the two arches adjusts the protrusion (2 mm per revolution of the screw) and allows the physiological movements of laterality during REM sleep.

Figure 3: Lateral movements with BestMAD.
hypopharyngeal collapse observed in the fiberoptic endoscopy with we specifically created was administered to assess the side effects with no compliance to the CPAP, BMI (Body Mass Index) ≤ 25 kg/m² Muller maneuver and a positive mandibular advancement test at the Computerized Tomography (CT) of the facial bones. All the selected BestMAD are shown in Tables 1 and 2.

eventually felt by the patient (difficulty in chewing and/or breathing, parameters. This entails the need to bring the threshold of statistical range 20-70) selected from those relating to the service for the temporomandibular joint pain, spinal pain, dizziness).

A total of 10 patients (9 males and 1 female, mean age 51.5 years, range 20-70) selected from those relating to the service for the diagnosis and treatment of sleep-disordered breathing of the Hospital "San Pietro Fatebenefratelli" in Rome and to the ENT department of the Hospital "San Salvatore" in L’Aquila from 2008 to 2013, were enrolled in the study. The inclusion criteria were: a diagnosis of OSA with no compliance to the CPAP, BMI (Body Mass Index) ≤ 25 kg/m², hypopharyngeal collapse observed in the fiberoptic endoscopy with Muller maneuver and a positive mandibular advancement test at the sleep endoscopy. All the patients underwent a preliminary ENT and dental examination, complete overnight cardio-respiratory polysomnography, medical questionnaire on the sleep-disordered breathing and related conditions, Epworth Sleepiness Scale (ESS) to measure daytime sleepiness, nasolaryngeal fiberoptic endoscopy with Muller maneuver, sleep endoscopy with mandibular advancement test, Computerized Tomography (CT) of the facial bones. All the selected patients were treated with the BestMAD. Patients no. 4, 6, 7, 8, 9 and 10 also underwent oropharyngeal surgery before starting the therapy with the BestMAD. All of them had an uvulopalatopharyngoplasty, and one of them also had a septoplasty (patient no. 10). A control polysomnography was repeated after six months and a questionnaire we specifically created was administered to assess the side effects eventually felt by the patient (difficulty in chewing and/or breathing, drooling, xerostomia, dental, lingual, gingival and/or mandibular discomfort, headache, changes in occlusal, masseter and/or temporomandibular joint pain, spinal pain, dizziness).

Results

Clinical data collected before and after 6 month of treatment with BestMAD are shown in Tables 1 and 2.

With regard to adherence to the treatment and side effects, 8 patients claimed to have used the BestMAD for the entire duration of nocturnal rest, while the remaining 2 only for a few hours at night. Six of 10 patients complained of xerostomia, 6 of drooling, 4 of temporomandibular joint pain, 2 of dental discomfort, 2 of mandibular discomfort, 2 of respiratory irritation and 2 of masseter pain.

Patients

Figure 4: The proprioceptive indicator of the BestMAD is a tongue perforated platform, with holes of increasing diameter, which starts from the top of the superior arch of the device and reaches the anterior part of the hard palate to induces a continuous stimulation of the tongue.

Figure 4: The proprioceptive indicator of the BestMAD is a tongue perforated platform, with holes of increasing diameter, which starts from the top of the superior arch of the device and reaches the anterior part of the hard palate to induces a continuous stimulation of the tongue. **Figure 4**

Table 1: Clinical data before starting the therapy with Best-MAD. AHI: Apnea-Hypopnea Index. RDI: Respiratory Disturbance Index. ODI: Oxygen Desaturation Index. ESS: Epworth Sleepiness Scale.

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<th>Snore ind (h)</th>
<th>ODI (h)</th>
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Table 2: Clinical data after 6 months of therapy with Best-MAD. AHI: Apnea-Hypopnea Index. RDI: Respiratory Disturbance Index. ODI: Oxygen Desaturation Index. ESS: Epworth Sleepiness Scale.

<table>
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Table: Clinical data after 6 months of therapy with Best-MAD. AHI: Apnea-Hypopnea Index. RDI: Respiratory Disturbance Index. ODI: Oxygen Desaturation Index. ESS: Epworth Sleepiness Scale.
Conclusions

In conclusion, the BestMad has proved to be a good choice among the many oral devices available on the market, either alone or in combination with other procedures, for the treatment of selected patients with OSA.

References


